Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Additive Effect of Acupuncture Combined with Extracorporeal Shock Wave Therapy Versus Shock Wave Therapy Alone in the Treatment of Plantar Fasciitis : a clinical trial study

Protocol summary

Study aim

Determining the additive effect of acupuncture combined with shockwave therapy versus shockwave therapy alone in the treatment of plantar fasciitis; and comparing pain and disability levels—measured before treatment, immediately after treatment (at 2 weeks), and four weeks after the start of treatment—between the shockwave-only method and the combined shockwave and acupuncture approach.

Design

Patients presenting with sole-of-the-foot pain persisting for more than one month will be referred to the Physical Medicine Department at the Ahvaz University of Medical Sciences medical center; the diagnosis of plantar fasciitis will be confirmed through clinical and/or radiological evaluations. Following initial assessments, 74 patients—selected based on inclusion and exclusion criteria—will be assigned via a random number table (using a double-blind randomization method) to one of two groups: one receiving shockwave therapy and the other receiving a combination of shockwave therapy and acupuncture. Instruments to be used: FADI and the VAS questionnaire.

Settings and conduct

Physical Medicine Department, Ahvaz University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of plantar fasciitis presenting with localized pain in the sole of the foot—particularly morning pain—persisting for at least one month. Exclusion criteria: Inflammatory diseases such as rheumatoid arthritis; history of direct trauma (with or without fracture of the foot bones); pregnancy; and a history of injections into the plantar fascia or incomplete courses of shockwave therapy or acupuncture within the preceding two months.

Intervention groups

One group will undergo shockwave therapy, while the other will receive a combination treatment of shockwave therapy and acupuncture.

Main outcome variables

Age Gender BMI Occupation Comorbidity Treatment type Pain Disability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260811070621N1**
Registration date: **2026-10-22, 1405/07/30**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-22, 1405/07/30**
Update count: **0**

Registration date

2026-10-22, 1405/07/30

Registrant information

Name

Atieh Lal vazifeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-31, 1405/06/09

Expected recruitment end date

2026-12-01, 1405/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Additive Effect of Acupuncture Combined with Extracorporeal Shock Wave Therapy Versus Shock Wave Therapy Alone in the Treatment of Plantar Fasciitis : a clinical trial study

Public title

Comparison of the Additive Effect of Acupuncture Combined with Extracorporeal Shock Wave Therapy Versus Shock Wave Therapy Alone in the Treatment of Plantar Fasciitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Plantar fasciitis (pain in the sole of the foot—particularly in the morning) patients who have suffered from this pain for a month.

Exclusion criteria:

Inflammatory diseases such as rheumatoid arthritis; A history of direct trauma—with or without fracture of the metatarsal bones A history of injections into the plantar fascia Incomplete shockwave therapy within at least the past two months Incomplete acupuncture within at least the past two months Pregnancy

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

The allocation sequence will be generated using permuted block randomization with a block size of 4 and a 1:1 allocation ratio between the intervention and control groups. This process will be carried out using SPSS software by an independent statistician who is not involved in participant enrollment, assessment, or intervention delivery; the allocation list will not be disclosed to the principal investigators until the study concludes. To ensure allocation concealment, sequentially numbered, opaque, sealed envelopes will be used. These envelopes will be prepared by an independent individual and stored in a secure location. Upon the enrollment of an eligible participant—and only after confirming inclusion criteria and obtaining informed consent—the envelope corresponding to the next sequence number will be opened by an individual not involved in outcome assessment or intervention delivery to reveal the assigned group. This process ensures that both researchers and participants remain unaware of the group assignment until the moment of allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

Following the acquisition of written informed consent and the patient's enrollment in the study, individuals are assigned to one of two groups—either the intervention group (routine shockwave therapy plus acupuncture) or the routine treatment group (shockwave therapy)—using a random number table. The randomization process is double-blind; participants, those assigning individuals to groups, and outcome assessors (the treating physician) remain completely unaware of the group allocations. Blinding is achieved through the use of opaque, sealed envelopes, each containing a unique code designating either the intervention or control group. Upon enrollment, each participant is assigned an envelope that determines their group placement. To implement the treatment protocol, Individual A administers shockwave therapy to all patients, while Individual B treats a subset of patients based on acupuncture groupings; consequently, Individual A—the physician in charge of the study—is blinded. The individuals responsible for data collection and statistical analysis, the person drafting the manuscript, and the data monitoring committee are also blinded, as they remain unaware of the defined codes.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

Ethics Committee, Ahvaz University of Medical Sciences, Golestan Highway

City

Ahvaz

Province

Khouzestan

Postal code

6135815751

Approval date

2026-08-31, 1405/06/09

Ethics committee reference number
IR.AJUMS.REC.1405.254

Health conditions studied

1

Description of health condition studied
plantar fasciitis
ICD-10 code
M72.2
ICD-10 code description
Plantar fascial fibromatosis

Primary outcomes

1

Description
Comparison of the additive effect of acupuncture to shockwave therapy versus shockwave therapy alone in the treatment of plantar fasciitis: A clinical trial
Timepoint
Before treatment, immediately after treatment (2 weeks), and 4 weeks after the start of treatment.
Method of measurement
Foot and Ankle Disability Index (FADI) and VAS questionnaire form

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: shockwave therapy
Category
Treatment - Devices

2

Description
Intervention group: shockwave+ acupuncture
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Imam Khomeini Hospital
Full name of responsible person
Atieh Lal Vazifeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
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Abdollah Rafiei
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available